



OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

# Review of the Common Rule and its Application

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# Learning Objectives

- Describe the basics of when to apply the Common Rule
- Understand and apply the regulatory definition of human subjects research for the purpose of the Common Rule
- Learn about exemptions to the Common Rule and how to apply them
- Understand when IRB review is required by the Common Rule



# When Do the Regulations Apply?

The HHS regulations apply to:

- **Non-exempt human subjects** research that is **funded by HHS**
- Human subjects research at institutions that elect for it to fall under the Common Rule (“**checking the box**”)
  - ✓ The “check the box” feature remains on the assurance (for now...)
  - ✓ The public will learn about any changes to the assurance process before they are implemented and will have a chance to comment on the proposed changes



# What Activities are Non-exempt Human Subjects Research?

To determine if your project is **non-exempt human subjects research**, ask these questions **in this order**:

1. Does the activity involve *Research*?
2. Does the research involve *Human Subjects*?
3. Is the human subjects research *Exempt*?



# Determining When the Common Rule Applies

**Is it  
research?**



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# Does the Activity Involve Research?

*Research refers to a **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge** ...*

§46.102(l)

There are 4 types of activities deemed not to be research



# Activities Deemed Not to be Research

1) Scholarly and journalistic activities

*[Government functions with separately mandated protections]*

2) Public health surveillance activities

3) Information collection for criminal justice purposes

4) Operational activities for national security purposes



# Scholarly and Journalistic Activities

*Collection and use of information that is only about specific individuals*

- Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- Excludes certain **activities**, not entire academic fields





# Public Health Surveillance Activities

Limited to those:

- Conducted by a **public health authority**
- Are necessary to **identify, monitor, assess, or investigate** potential public health signals, onsets of disease outbreaks, or conditions of public health importance, and
- Provide **timely situational awareness and priority setting** during the event or crisis that threatens public health



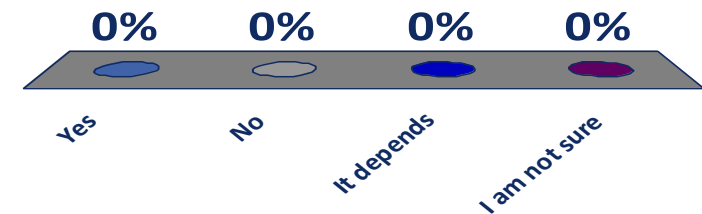
# Test Your Knowledge

A team of physicians treat a patient with an unusual presentation of disease. They run a variety of tests and procedures but are unable to resolve the discrepancies.

They write a case summary of their observations and submit it to a medical journal for publication.

**Is this research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**

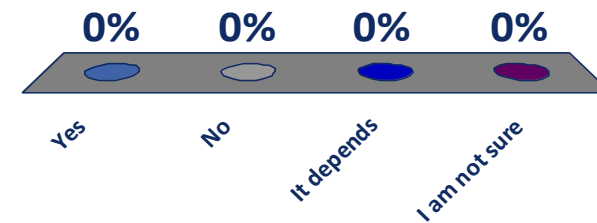


# Test Your Knowledge

A political science professor wishes to study how race and gender considerations affected policy decisions of state governors. He plans to conduct extensive interviews with current and past governors to find out how much race and gender considerations might have influenced policy outcomes.

**Is this research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**

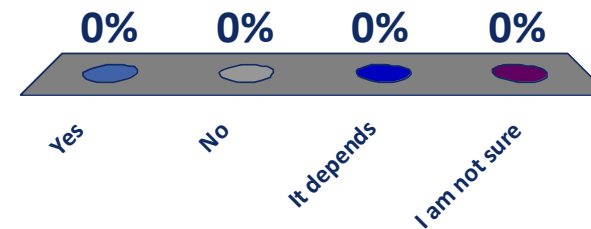


# Test Your Knowledge

A physician reports an outbreak of an unusual type of meningitis. The public health authority in the area plans to collect the patients' medical and demographic information to document trends, and identify signals and risk factors as a way to better manage this potential public health crisis.

**Is this research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**

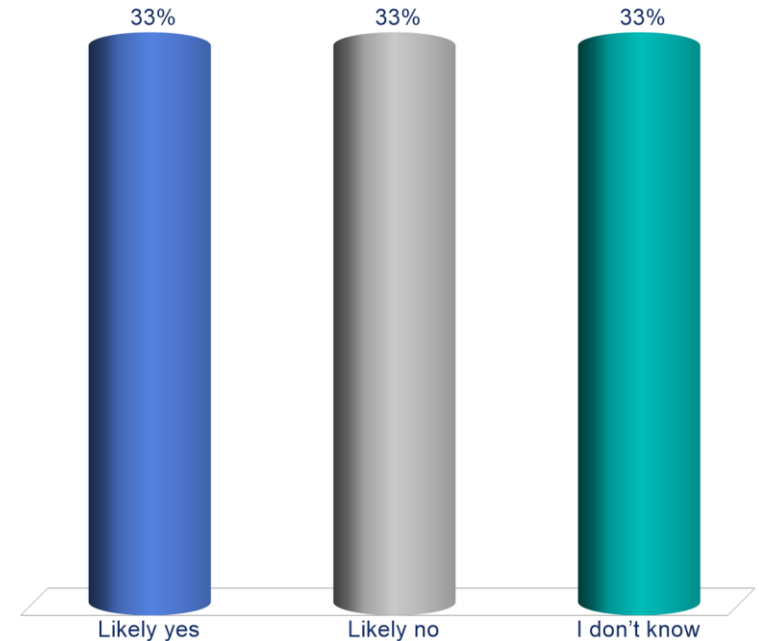


# Test Your Knowledge

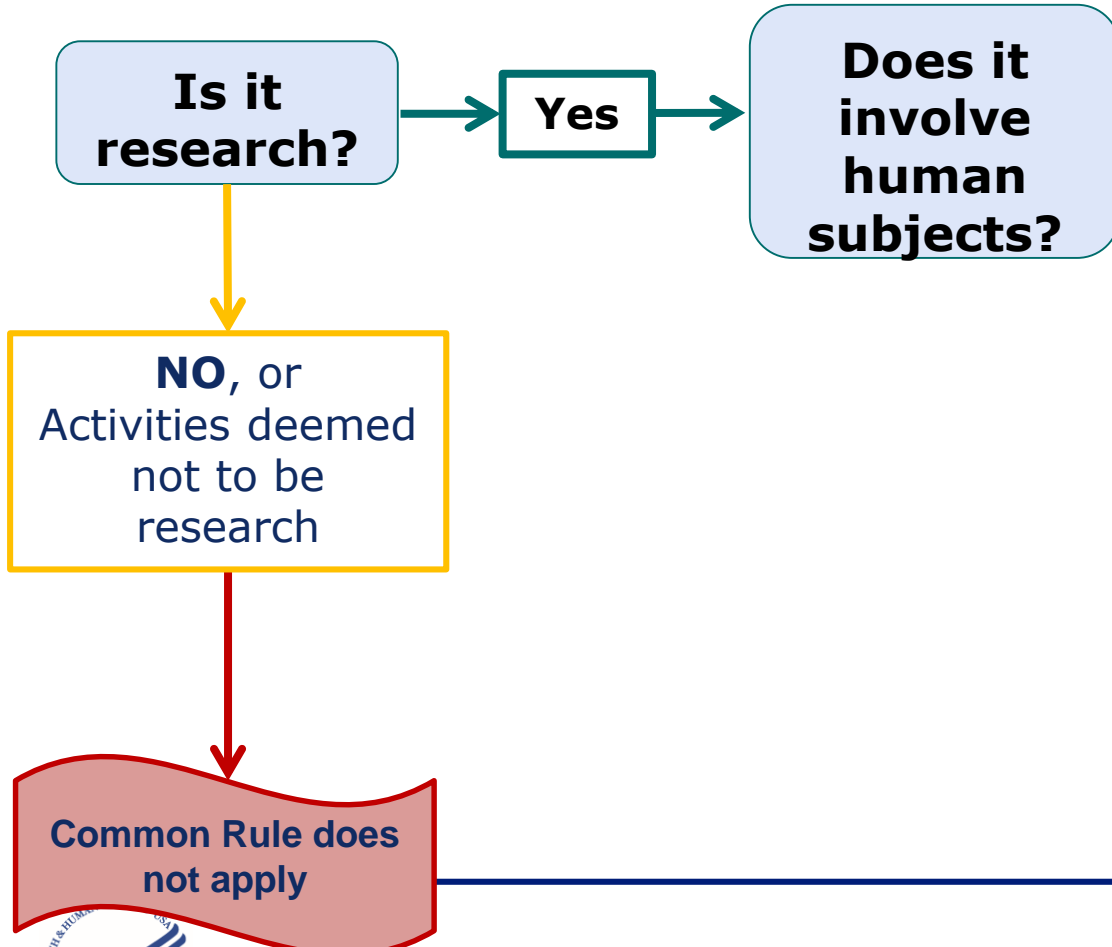
CDC and state public health officials collect blood, stool, and information from passengers aboard a cruise ship that had an outbreak of a GI illness. Results will be used to design preventative measures and best practices to avoid future outbreaks on other cruises.

**Is this research?**

- A. Likely yes**
- B. Likely no**
- C. I don't know**



# Determining When the Common Rule Applies



# Does the Research Involve Human Subjects?

## Human subject:

a **living** individual **about whom** an investigator conducting research

- Obtains **information or biospecimens** through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens;

or

- Obtains, uses, studies, analyzes, or generates **identifiable private** information or **identifiable biospecimens**

§46.102(e)(1)



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# Associated Terms and Concepts

- **Intervention** includes both physical procedures by which information or biospecimens are gathered...and manipulations of the subject or the subject's environment performed for research purposes
- **Interaction** includes communication or interpersonal contact between investigator and subject
- **Identifiable biospecimens or private information:** biospecimens or private information for which the identity of subject is or may readily be ascertained by the investigators or associated with the information





# The Evolving Concept of “Identifiability”

- Federal agencies commit to collaborate at least every four years to:
  - Re-examine the meaning of identifiability
  - Determine analytic techniques capable of generating identifiable private information or biospecimens

§46.102(e)(5)-(7)

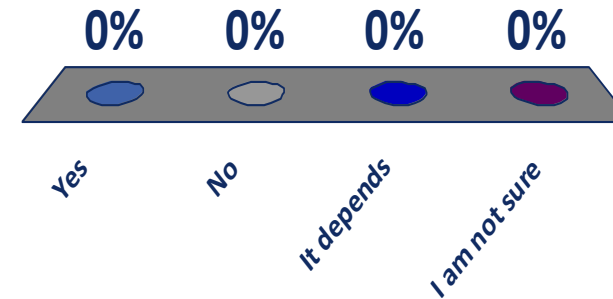


# Test Your Knowledge

A researcher wants to observe online chatroom behavior in various publicly accessible environments. She periodically posts opinion questions to the chatrooms to elicit chat room responses.

**Is this human subjects research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**

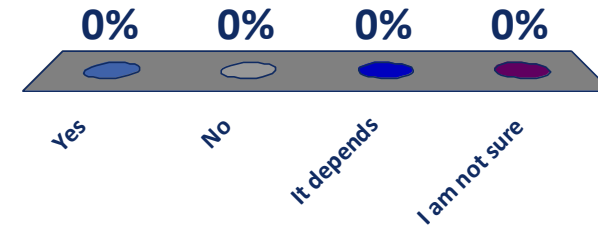


# Test Your Knowledge

For the purpose of your research, you have contracted a commercial survey firm to collect specific information for you. The commercial firm will only provide you with coded data with no identifying information.

**Is this human subjects research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**

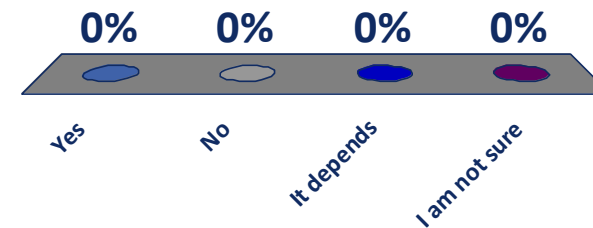


# Test Your Knowledge

You are working in a large collaborative study. Another investigator will give you coded biospecimens (collected for this current research) for analysis. When you are done, your analysis will be returned to the investigators that provided them.

**Is this human subjects research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I am not sure**



# Research with Biospecimens or Private Information That is NOT Human Subjects Research

If research involves **only** coded biospecimens or private information **and** meets both of the following:

1. Is not collected specifically for the research in question,  
**and**

2. Investigator(s) cannot readily ascertain identity of the individual(s) to whom data/specimens pertain,

No *interaction* or *intervention*!

No *identifiable* materials!

...then it is **NOT** human subjects research.

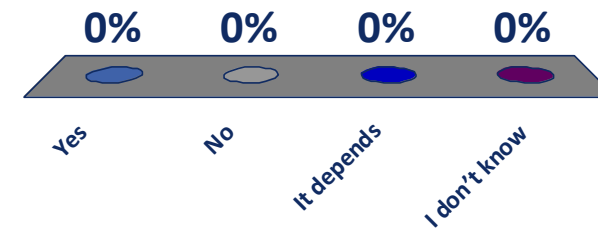


# Test Your Knowledge

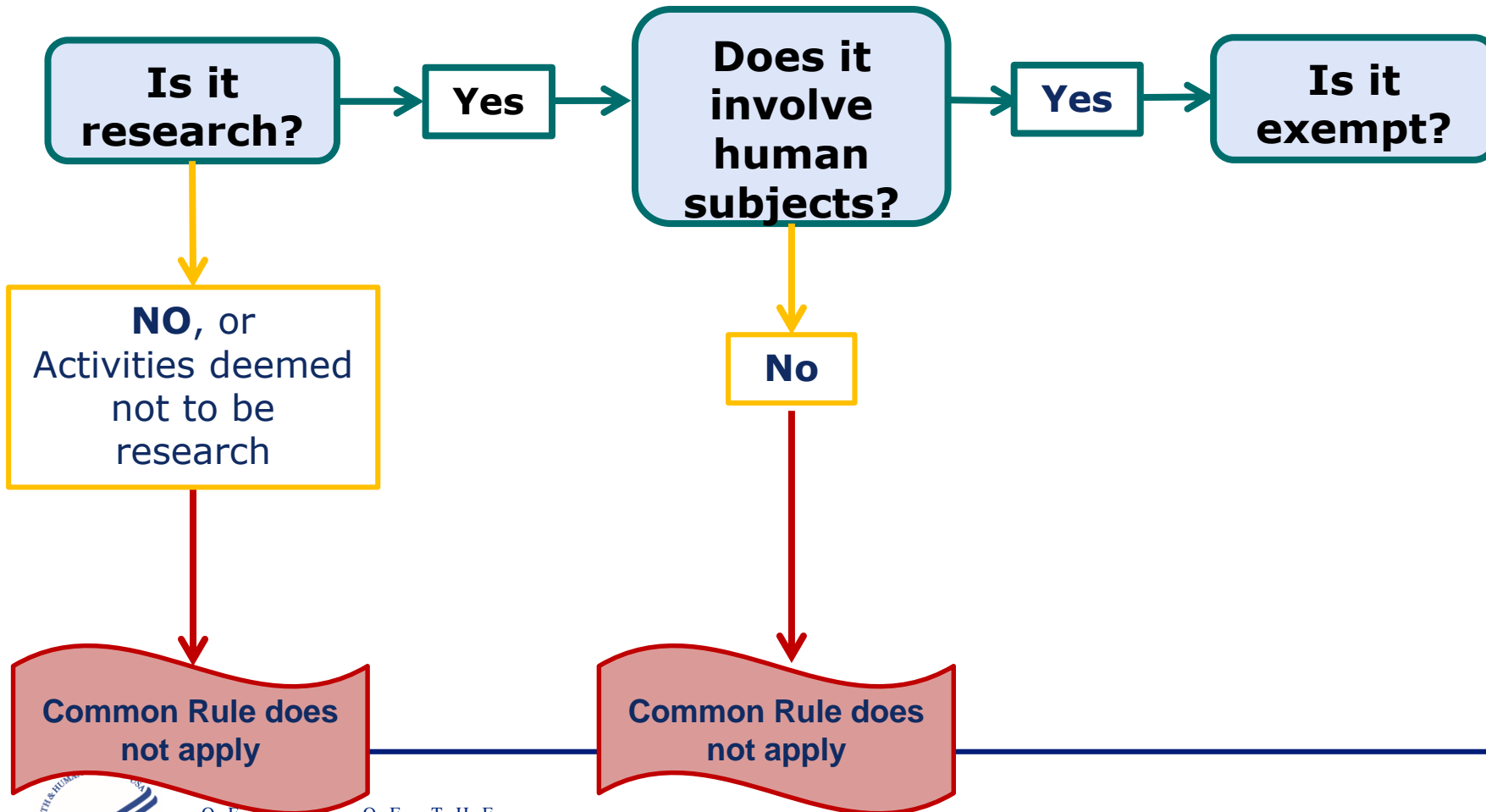
A cancer researcher plans to use leftover tissue samples from tumors that were removed from patients during surgery. The samples would otherwise be discarded. The tissue samples will be provided without any patient identifiers.

**Is this human subjects research?**

- A. Yes**
- B. No**
- C. It depends**
- D. I don't know**



# Determining When the Common Rule Applies



# “Exempt” Research

What does it mean for a research project to be exempt?

- It is human subjects research
- It meets the criteria of one of the exemptions listed in §46.104
- If determined to be exempt:
  - Common Rule does not require standard IRB review
    - Some exemptions require a limited IRB review as part of the exemption determination
    - Institutions may elect to review these projects as a matter of institutional policy
- Institutions should designate who shall determine whether a research project qualifies as exempt





# Exemptions

Exemption 1: Normal educational practices in established educational settings

Exemption 2: Educational tests, surveys, interviews, or observation of public behavior

Exemption 3: Benign behavioral interventions

Exemption 4: **Secondary** research use of biospecimens or information for which informed consent is not required

Exemption 5: Evaluation of public benefit and service programs

Exemption 6: Tasted and food quality evaluation & customer acceptance studies

Exemption 7: Storage and maintenance of identifiable materials for unspecified **secondary** research with broad consent

Exemption 8: **Secondary** research use of stored identifiable materials with broad consent

§46.104(d)(1-8)



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# Exemption 1

Normal educational practices in established or commonly accepted educational settings

- Must not be likely to adversely impact:
  - Students' opportunity to learn required educational content, or
  - The assessment of educators who provide instruction

§46.104(d)(1)



# Exemption 2

Research that only includes interactions involving educational tests, surveys, interviews, and observations of public behavior, when:

- Information cannot be linked to subjects,  
**or**
- Information disclosure would not place subjects at risk of certain harms (including educational advancement),  
**or**
- Identifiable information recorded with limited IRB review for adequate privacy and confidentiality protections under §46.111(a)(7)

§46.104(d)(2)

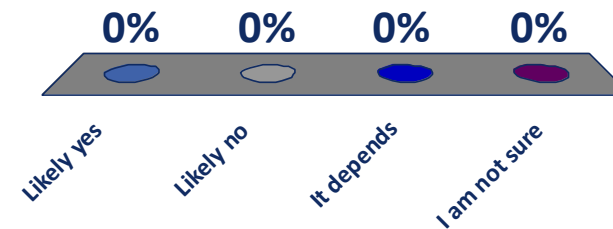


# Test Your Knowledge

An investigator wants to study whether calming music improves cognitive performance in adults. One group of subjects will take a cognitive test in a quiet room, and the other group will take it in a room with calming background music. The investigator will collect the tests without any individually identifiable information.

**Would this research meet the criteria for the revised exemption 2?**

- A. Likely yes**
- B. Likely no**
- C. It depends**
- D. I am not sure**



# Exemption 3

Research involving **benign behavioral interventions** with **adults** who **prospectively agree** when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, when

- Information cannot be linked to subjects,  
**or**
- Information disclosure would not place subjects at risk of certain harms,  
**or**
- Identifiable information recorded with limited IRB review for adequate privacy and confidentiality protections under §46.111(a)(7)

§46.104(d)(3)



# Exemption 3, cont.

## Benign behavioral interventions:

These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and investigator has no reason to think the subjects will find the interventions offensive or embarrassing

- Includes authorized deception research

§46.104(d)(3)(ii)-(iii)

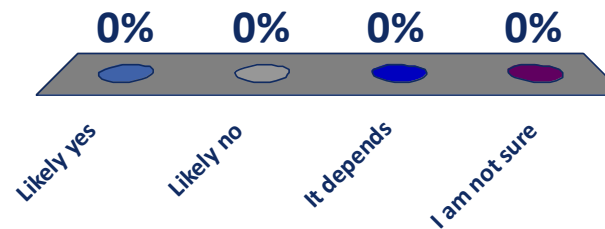


# Test Your Knowledge

An investigator wants to study whether calming music improves cognitive performance in adults. One group of subjects will take a cognitive test in a quiet room, and the other group will take it in a room with calming background music. The investigator will collect the tests without any individually identifiable information.

**Would this research meet the criteria for the revised exemption 3?**

- A. Likely yes**
- B. Likely no**
- C. It depends**
- D. I am not sure**



# Exemption 5

## Public benefit and service programs research and demonstration projects

- Applies to such Federally conducted or supported research
- Requires that Federal agency publish a list of projects covered by this exemption prior to commencing the research

§46.104(d)(5)



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# Exemption 6

Taste and food quality evaluation and consumer acceptance studies

§46.104(d)(6)



# Exemptions and Certain Vulnerable Populations

There are times when you cannot use exemptions

- **Research with Prisoners**

- Generally, exemptions do not apply to research with prisoners
  - *Exception:* research aimed at a broader population that incidentally includes prisoners

- **Research with Children**

- Exemption 2 does not apply for surveys, interviews, or observation of public behavior if investigators are involved in the activity
  - It can apply for educational tests
  - Cannot use provision to collect identifiable information with limited IRB review (2(iii))
- Exemption 3 does not apply to research with children



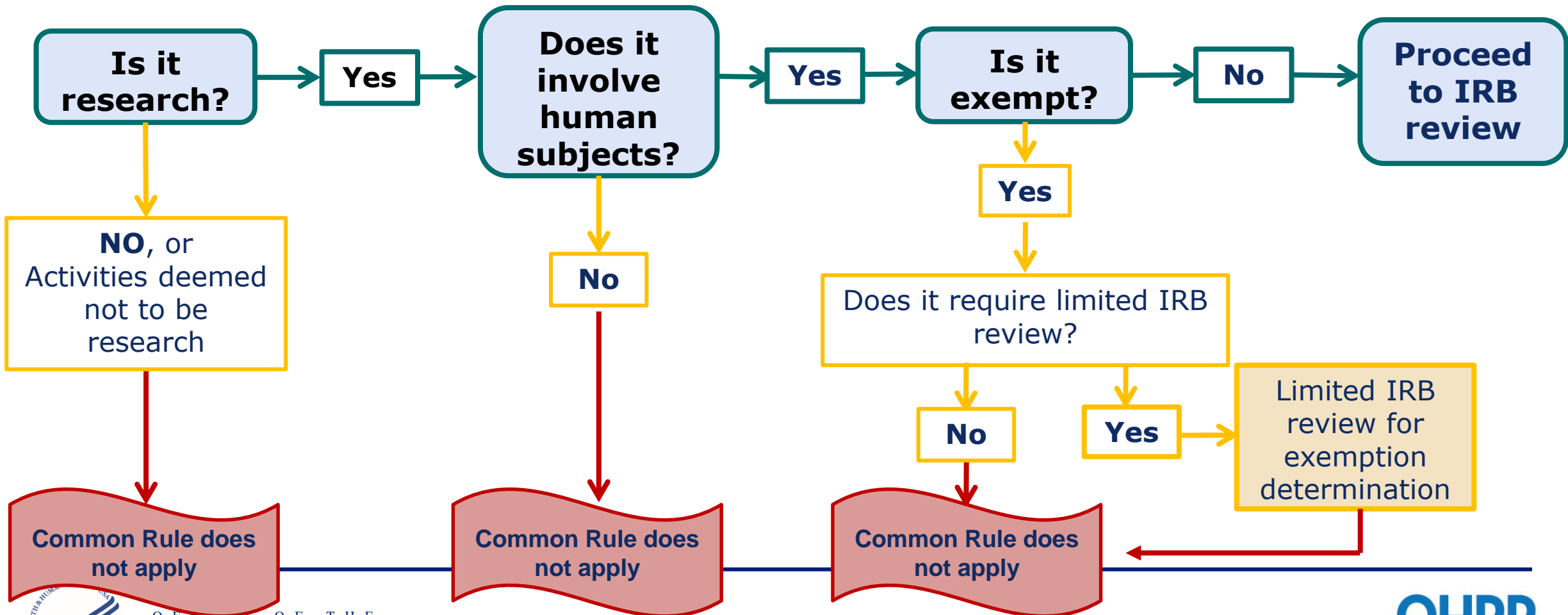
# Limited IRB Review

Required for **exemptions 2(iii), 3(i)(C), 7, and 8**

- **Exemptions 2(iii) and 3(i)(C) review:**
  - For privacy and confidentiality protection under §46.111(a)(7)
- **Exemptions 7 and 8 review:**
  - For safeguards related to privacy and confidentiality protection, and broad consent
- Must be conducted by IRB member(s)
- Expedited review mechanism can be used
- No continuing review required



# Determining When the Common Rule Applies



Please refer to the text of the revised Common Rule available on [OHRP's website](#) for a complete and accurate description of the regulatory requirements



[illegible]

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